

June 7, 2002

W-01-14 Comments Clerk
U.S. Environmental Protection Agency
Water Docket (MC-4101)
1200 Pennsylvania Avenue, NW.
Washington, DC, 20460.

To Whom it May Concern:

On behalf of over 22,000 small and rural drinking water utilities, the National Rural Water Association (NRWA) is pleased to submit comments on the Environmental Protection Agency's "Announcement of the Results of EPA's Review of Existing Drinking Water Standards." NRWA represents the voice of small and rural utilities with a sustaining membership of over 41% of community water systems. No other organization represents such a large proportion of regulated entities and requests the Agency to seriously consider the suggestions contained herein.

We thank you for the opportunity to provide comments regarding this important matter.

Sincerely,

Robert Johnson
Chief Executive Officer

Attachment

National Rural Water Association

6 Year Review Comments

On behalf of over 22,000 small and rural drinking water utilities, the National Rural Water Association (NRWA) is pleased to submit comments on the Environmental Protection Agency's "Announcement of the Results of EPA's Review of Existing Drinking Water Standards." NRWA represents the voice of small and rural utilities with a sustaining membership of over 41% of community water systems. No other organization represents such a large proportion of regulated entities and requests the Agency to seriously consider the suggestions discussed below. We request that as the Agency deliberates about certain issues to always ask themselves, "what has NRWA said about this matter?" If the comments below do not address a certain issue the Agency is evaluating, we would welcome the opportunity to provide a small system perspective on behalf of our members. Please do not hesitate to contact our organization if you need more information, have a need for joint studies or projects or would like to know more about how EPA regulations may impact a small system.

1. Do Not Reevaluate Fluoride

The Agency also requested comment on whether or not to reassess the Fluoride MCL and the fluoridation process. We agree with the American Dental Association and the Center for Disease Control that dental fluorosis is a cosmetic problem and the Agency should not lower the fluoride MCL from 4 mg/L to 2 mg/L. The practice of fluoridation has always been left up to the states and we prefer no mandatory requirement for systems to fluoridate at the federal level.

The public health service recommended fluoridation level to be used at schools is 3 mg/L. If EPA lowers the MCL, then schools currently fluoridating may have to decide between eliminating the fluoride addition because the level would be too low to be effective over a short school day or be in non-compliance with EPA (but complying with PHS recommendations).

The EPA should revise the PN requirement to remove the mandatory public notification requirements for exceedances of the fluoride MCL. Since EPA is saying that exceedances of secondary MCL's do not impact the health they should not require public notice.

Do not require more frequent monitoring for systems that fluoridate. All State primacy agencies have monitoring requirements for systems that fluoridate. All issues associated with fluoride must stay at the local level because of the broad diverse opinion related to the subject.

2. Research and Development of New Analytical Methods

In the Agencies protocol for analytical methods there is a mechanism for additional analytical research. The United States Geological Survey (USGS) is in agreement that radium and gross alpha methods are not accurate or precise and clearly new methods need to be developed that can meet the detection limits specified by the Agency with precision. There are documented problems in Minnesota and Colorado when gross alpha values exceed the MCL but when the sample is speciated and all alpha emitters are summed, the combined values do not exceed the gross alpha MCL. In addition EPA promulgated a MCL regulating Uranium eighteen

months earlier (Dec. 2000) and has yet to provide an approved analytical method to identify the presence/absence of the contaminant.

3. Atrazine

The atrazine risk assessment has been released by the EPA Office of Pesticides. The atrazine standard should be revised to reflect the new risk assessment information.

4. Fix Rule Implementation and Monitoring Problems

We disagree with the Agency decision not to correct implementation problems in the regulations. Based on the findings contained in EPA's State Primacy Agency Data Verification (DV) program, it is clear that rules with implementation problems are not being enforced. We suggest that the Agency consult with the individuals responsible for conducting and evaluating the State DV program to identify other implementation issues that NRWA has not mentioned below. In conjunction with consulting the DV team(s), the Agency should evaluate each State DV Report to identify common rule implementation problems. This approach would provide the Agency with sound evidence where problems exist rather than relying on surveys. Since the Agency has decided that no revisions are necessary at this time, they should use the available resources to fix problems in the rule that are not being protective of public health. In addition to using the DV Reports as a tool for identifying common implementation problems our members have identified the following issues as concerns for small and rural systems; they have been listed in order of priority:

- (i) *Evaluate the CCR effectiveness and revise requirements*

NRWA recognizes that Consumer Confidence Reports are an important part of the consumer/provider relationship and that the American public must be educated about the safety of their drinking water. However, the CCRs are very costly. Small systems could use the resources dedicated to this annual report to comply with all the new EPA regulatory requirements, improve drinking water quality and upgrade aging infrastructure. Our members have field experience and field data to prove that the current CCRs are ineffective in communicating drinking water information to consumers. The CCR regulatory requirements are burdensome and confusing to the general public.

NRWA and the State Associations are interested in participating in a joint study/partnership to identify the necessary revisions to the CCR to enhance the effectiveness and decrease costs. We believe that this is a "win-win" proposal. With the technical expertise of our field staff, we can provide the grass roots knowledge that will make CCRs effective, communicate the right message, and increase public confidence in the water they drink. It also has the potential to decrease costs which will free up revenue for funding other upgrades that are much more protective of public health. We understand that the CCRs have drawn some criticism from a variety of organizations that represent a broad array of individuals (United States Congress, trade associations, environmental organizations, State primacy agencies, and drinking water utilities) and we would like to be the leader in assisting EPA in this reevaluation process.

(ii) Relax the lead and copper monitoring requirements

The Agency should complete an evaluation of the lead and copper monitoring requirements in an effort to relax the requirements as necessary. If a system has proven through monitoring that there has never been a lead and copper problem, the new plumbing code requirements for materials which require lead free solder and plumbing fixtures should preclude there ever being a problem. In this case, NRWA recommends that a system be eligible for minimal water quality testing, for instance, to show that the water quality has not changed, and that there is no need to collect further lead and copper samples.

(iii) Remove barriers in the drinking water SRF process

The Agency should take a close look at the requirements in the drinking water state revolving loan fund to more closely align the funding process to small system needs. Presently small systems (often the systems in most need of funding) are discouraged from applying for the funds because there are too many regulatory barriers to get through. If the Agency would make it easier to apply for and obtain the funding, more applications would be completed by small systems. If State requirements were made easier, then more systems would be approved at a faster rate and more systems would have the resources to provide safe drinking water. At the present time the SRF process is often working against small systems because while they are waiting for funding they typically get penalized as a Significant Non-Complier (SNC) and funds are being used to pay the fines. Specifically, we are requesting the Agency to evaluate the following four areas:

- Regulatory – too much complexity for obtaining funds
- Rating applications – Often 1 large system project gets majority of funding instead of small systems that stay too far down the list to become priorities
- Affordability criteria – these criteria need to be reevaluated for small system loan acceptability

The Agency has recently released a document for evaluating the State SRF program; we suggest that a similar effort be completed for small drinking water systems.

(iv) Evaluate occurrence database for alternate monitoring requirements

With all the new monitoring and reporting requirements EPA should reduce monitoring when previous monitoring indicates no contamination and rely on other less expensive surrogate parameters. The Agency should not require resources be spent on contaminant monitoring programs that have little practical need to continue monitoring.

(v) Fix the inorganic compliance determination language.

EPA clearly intended for the compliance determination language in 40 CFR 123(i)(1) to require systems that exceed the MCL to begin quarterly monitoring and determine compliance after the system has the opportunity to collect 3 additional samples. The Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring Rule preamble

describes EPA's intent. Clearly the Agency intended that compliance with all chemical contaminants be calculated the same. Apparently, the compliance language from the Arsenic Proposed Rule (June 22, 2000) was inadvertently placed in the IOC section (40 CFR 123.(i)(1)) but new more concise language was put into the SOC and VOC sections. The preamble in the final rule is consistent with the revised language that was finalized for the SOC's and VOC's in 40 CFR 124. The preamble states that, "**Systems monitoring annually or less frequently whose sample result exceeds the MCL for inorganic contaminants listed in 141.23(c) or whose sample result exceeds the trigger level of organic contaminants listed in 141.24(f) or 141.24(h) must revert to quarterly sampling in the next quarter. The system will not be considered in violation of the MCL until it has competed one year of quarterly samples.**" For consistency with all other chemical and radiological rules, NRWA recommends that the compliance language finalized for the SOCs and VOCs (40 CFR 124) in the arsenic final rule (January 22, 2001) be adopted for the IOCs.

(vi) *Expand small system representation in the rule making process.*

On behalf of 22,000 small and rural utilities we would like to be more integrated into the rule making process. Our vision goes beyond the mandatory requirements that EPA must complete under the SBREFA and other stakeholder outreach programs. We are proposing that the Agency invite us to key workgroup meetings to discuss drinking water rule progress. This involvement would benefit both parties. EPA would have the benefit of hearing how different aspects of rules will impact small and rural utilities; and NRWA will have the benefit of knowing the potential regulatory requirements to prepare our field staff to be cognizant of other issues that may impact the technical assistance provided in the field.

5. Possible Changes to the MCL/MCLG for Certain Contaminants

We basically agree with the EPA's decision not to change the MCLG/MCL values for the four contaminants, beryllium, chromium, oxamyl, and picloram for which the health effects basis has changed. With a few exceptions we are also in agreement with the Agency's "no revision" and "further research" categories. The Agency conducted a systematic process to review information related to the existing regulated contaminants. However, there are two aspects of the analyses leading to these decisions that are of concern to us. These are:

1. The use of uncertainty factors in the MCLG/MCL determinations and in the decision process, such as the factor of 10 used in the original beryllium MCLG determination, can lead to overly conservative decisions and values especially when considered in the context of the compounding of several factors in a specific regulatory development process. As a part of its careful examination of the issues involved in the regulatory process, the NRWA commissioned the preparation of a white paper to clearly identify the steps in development of a regulation in which the precautionary principle (the use of safety and/or uncertainty factors) is applied, the magnitude of the safety factors introduced, and those aspects of this process that may need modification (See Attachment 1 for a copy of the paper). The NRWA would urge the Agency to follow the recommendations of this paper which are as follows:

- Risk and benefit estimates should practice full disclosure and provide complete transparency by listing all the precautionary assumptions embedded in a risk reduction benefits assessment
- Remove precautionary science policy assumptions and provide central tendency estimates for their risk reduction and associated benefits estimates (as well as probability distribution information or, at a minimum, reasonable lower and upper bounds).
- Comprehensive sensitivity analyses should be applied as an essential tool to help reveal the individual and collective impact of precautionary assumptions on the risk and benefits findings presented to decision-makers, regulatory reviewers, and other stakeholders.

If these principles were followed in the current beryllium determination, we feel there would be clear justification to discontinue use of the "management factor" of 10 with a concomitant increase in the MCLG.

2. When the opportunity to raise an MCL value without sacrificing health protection occurs, as is the case with beryllium and picloram, we urge the Agency to do so even though the cost analysis using the 16-state cross section analysis does not indicate significant savings. To those systems affected, especially if they are small, the cost savings individually can be very significant although the aggregate may not be large. With the ever-increasing regulatory cost burden on small systems any opportunity to relieve this burden should not be overlooked, especially when a 16-state sample is used for the analysis and may not be representative of the entire country.

We also request the agency to make glyphosate a priority for review as soon as the risk assessment is released. Based on EPA occurrence estimates, the contaminant is rarely detected (<0.1%) at concentrations 1000 times lower than the MCL. Also based on EPA estimates, only about 19,000 people are being exposed to this contaminant (at concentrations 1000 X lower than the MCL). The cost of analyzing for this single analyte contaminant (the lab has to run a separate test for this single contaminant) is very expensive. EPA must take this cost/benefit relationship into consideration during the deliberation process. More importantly, preliminary evidence is suggesting this contaminant is a non-carcinogen. Based on the assumptions described above we are recommending this contaminant be deregulated.

Lastly we would like EPA to better define the definition of "significant". Throughout the Notice of Intent and the Stakeholder process EPA has repeatedly indicated they would revise a contaminant or take on "other regulatory revisions" if there is potential for "significant" increase to public health. At the Stakeholder meeting EPA indicated that a factor of 2 would not be significant for changing the MCLG. What is significant? Is 5 significant? Is 10 significant? And what is significant for evaluating "other regulatory revisions"?

Attachment 1

NRWA White Paper:

**Blending Science with Policy: Precautionary Assumptions and
Their Impact on Benefit-Cost Analyses and Drinking Water Standards**

**National Rural Water Association (NRWA)
Regulatory Policy Development Project**

**White Paper:
Blending Science with Policy: Precautionary Assumptions and
Their Impact on Benefit-Cost Analyses and Drinking Water Standards**

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Final Report
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1. Numerous useful comments and insights were contributed by Drs. Douglas Crawford-Brown (University of North Carolina) and David E. Burmaster (Alceon Corporation). Any remaining errors or omissions should be attributed to Bob Raucher. Dr. Raucher can be reached at 303-381-8000, or via e-mail at braucher@stratusconsulting.com.

Executive Summary

Under the 1996 Safe Drinking Water Act Amendments (SDWAA), benefit-cost analysis (BCA) is now an integral part of the regulatory development process in the United States. This paper reveals why and by how much benefits may be overstated when traditional precautionary science policy assumptions are embedded in the risk assessments that form the foundation for a benefits analysis.

Before the 1996 SDWAA, risk assessment was used in drinking water standards development only to identify the level at which “no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety” — in other words, to establish what the statute defines as a Maximum Contaminant Level Goal (MCLG). In this limited role of determining a “no risk level” for a contaminant concentration, risk assessors have been guided by precautionary science policy choices that err on the side of safety when facing the considerable uncertainties and variabilities that enter the risk assessment process. Using these conservative assumptions and other precautionary rules of thumb is consistent with the objective of identifying a concentration that poses no risk for even the most highly exposed and most sensitive individuals, including a margin of error.

However, when risk assessments are applied in a risk management context, the conservative assumptions embodied in the precautionary approach are likely to lead to misleading results. In a benefit-cost application, risk assessments need to be well grounded upon what is likely to occur; the risk assessment must revert back to the underlying science rather than the policy judgments inherent in the conservative science policy choices. Because BCA contributes to risk management deliberations on how stringently to set MCLs, it is contrary to good science and statutory directives to carry forward risk estimates that are significantly impacted by myriad precautionary science policy assumptions. The treatment of these uncertainties tends to inflate the level of risk posed by contaminants, and therefore leads to an overstatement of the benefits of regulations.

The degree to which risk reduction benefits are overstated (if at all) will vary considerably from contaminant to contaminant, depending on many factors. However, the illustrative examples shown in this paper indicate that it is not unreasonable to suspect that benefits derived using precautionary assumptions may be 10, 20, 100, or even many more times higher than one would expect at the mean or median of the benefits distribution.

In view of the potentially significant impact precautionary assumptions can have on estimated risks and associated BCAs, the following recommends are offered:

1. EPA and other entities that develop risk and benefit estimates should practice full disclosure and provide complete transparency by listing all the precautionary assumptions embedded in a risk reduction benefits assessment.
2. To the extent possible, EPA and other entities should remove precautionary science policy assumptions and provide central tendency estimates for their risk reduction and associated benefits estimates (as well as probability distribution information or, at a minimum, reasonable lower and upper bounds).
3. Comprehensive sensitivity analyses should be applied as an essential tool to help reveal the individual and collective impact of precautionary assumptions on the risk and benefits findings presented to decision-makers, regulatory reviewers, and other stakeholders.

Blending Science with Policy: Precautionary Assumptions and Their Impact on Benefit-Cost Analyses and Drinking Water Standards

Introduction

This white paper examines the use of “precautionary assumptions” and their implications for setting drinking water standards. The paper explores how “science” and “policy” must blend when mandates to protect public health come face-to-face with uncertainty about the risks posed by a contaminant. The focus here is on issues that arise in the context of how *risk assessments* derived using conservative assumptions are applied within the *risk management* context of benefit-cost analysis and standard setting.

When drinking water standards are being developed, regulators need to carefully weigh potentially sizable human health risk reduction benefits against the anticipated costs of a Maximum Contaminant Level (MCL). The estimated health benefits are typically based on science-based risk assessments that contain several critical uncertainties. Collectively, the manner in which these uncertainties are addressed within the risk analysis can have an overwhelming impact on the estimated level of risk reduction that a given MCL option is expected to generate.

In some instances, the scientific risk assessments are so affected by uncertainties that it is difficult to determine whether the most likely health benefits are trivially small, or whether they are large enough to constitute a wise investment in public health protection. These issues take on added significance when the regulations affect rural households served by small community water systems, because the cost of compliance per impacted household tends to be relatively high for these beneficiaries.

In such a policy-making context, the stakes are quite high. If we under-regulate, then we are exposing people to undue health risks. However, if we over-regulate, then we are imposing high costs that are disproportionate to the health benefit people are receiving (and we are misdirecting resources that otherwise might be applied to reducing risks in other areas of life).

Making prudent public health regulatory decisions in this high stakes context is especially challenging when the “science” underlying the risk estimates is embedded with many conservative assumptions that are established as a matter of “policy.” The use of

conservative “science policy” assumptions is guided by what is often referred to as the “precautionary principle.” The precautionary principle is sometimes defined differently by different entities and individuals (see below), but for the purposes of this white paper the term is used broadly to reflect an approach or philosophy that, in essence, calls for “erring on the side of safety” by using risk assessment protocols that are more likely to overstate a risk (rather than to under estimate it) when uncertainties and/or variabilities are present.

Policy-imposed conventions on how risk assessments are conducted with conservatism have merit in some risk policy applications (as described below). However, the cumulative impact of conservative science policy assumptions lead to health risk estimates that potentially are significantly overstated for drinking water contaminants in the relevant concentration range. This in turn leads to potentially significant over-estimates of the public health benefits of a potential MCL. This will create misleading benefit-cost comparisons and, in turn, may lead to regulatory decisions that are not well informed.

Accordingly, this paper examines how, and by how much, the use of conservative science policy assumptions can impact a risk estimate and the benefit-cost analysis that applies the risk results (and which, ultimately, is likely to affect the MCL selection). The objective is to reveal the potential impact of current practices and explore how science policy may need to be altered or re-interpreted when the resulting risk assessments are applied within the risk management contexts of benefit-cost analysis and standard setting.

A Basis for Erring on the Side of Safety: Where “Science” Ends and “Policy” Begins

When policies are made in the interests of protecting public health, officials typically need to make critically important decisions by relying on technical information that is incomplete and often highly uncertain. In such instances, “science” cannot provide clear-cut answers and policy-making requires taking account of many other considerations.

Where public health is at risk, there are prevailing moral codes and cultural values that suggest that society “err on the side of safety” to protect the innocent in the face of uncertainty. This core philosophy is deeply rooted in many of our nation’s social and legal institutions, and in the regulatory context it is embodied in what is sometimes

referred to as the precautionary principle. In short, it is part of the prevailing cultural belief system that is the fabric of our society.

When discussions are held on broad, philosophical terms, there is little debate about the importance of protecting public health and erring on the side of safety. However, the issues become far more complex and controversial when specific policy applications are being considered. When the stakes involved in making a poor regulatory decision are high if we err toward either too little or too much health protection (e.g., when compliance costs may be very high, and/or where the risk outcomes are irreversible), then several pragmatic concerns logically arise. Key issues include:

1. Are the individual and cumulative impacts of conservative science policy assumptions on the estimated risk and benefit outcomes transparent to analysts, decision makers, and stakeholders?
2. How much erring on the side of caution is embodied in the analyses? How far are the resulting risk and benefits estimates skewed upward to very low probability outcomes by the cumulative use of precautionary assumptions? How do the final risk and benefit estimates compare to more likely (higher probability) scientifically based estimates?
3. How much will it cost to provide a broad margin of safety? What is the benefit-cost comparison when considering the most likely range of anticipated health risk reductions, and how different is this from the benefit-cost findings derived when highly conservative risk estimates are used as the basis for the analysis?

Defining the “Precautionary Principle”

In this paper, we apply the term “precautionary principle” in the broad context in which uncertain science-based findings are (1) directly affected by policy decisions about how conservative assumptions are applied in risk assessments, and/or (2) interpreted within a risk management context in which policy-making consciously errs on the side of safety. In other words, for the purposes of this paper, the term precautionary principle is interpreted broadly to include conservative science policy assumptions that are embodied within risk assessments, and also the manner in which those risk assessments are interpreted within the decision-making framework of risk management.

Readers should note that in some writings, a distinction is made between the two facets noted above. For example, the Commission of the European Communities (CEC) refers to the precautionary principle only in the context of how decision-makers manage risks. The CEC notes that the precautionary principle “should not be confused with the element of caution that scientists apply in their assessment of scientific data” (CEC, 2000). In the European Union, the precautionary principle is seen as a risk management tool, not a risk assessment tool. There, the best science is used for the risk assessment, the uncertainty is assessed, and this information is given to the risk manager. It is only after this point that the precautionary principle is applied, as the decision-maker decides what to do in the face of this uncertainty. In the United States, the process is somewhat reversed, with precautionary assumptions influencing the risk assessment results upon which risk managers rely when making policy decisions. These issues are discussed below.

The Risk Assessment Context

The CEC (and others) make a key distinction between risk *assessment* and risk *management* when applying terms such as the precautionary principle. In reference to the former, some prefer to use terms such as “prudential approach,” “precautionary assumptions,” or “science policy” to reflect conservative assumptions that are embodied in risk assessments as a matter of policy:

The prudential approach is part of risk assessment policy which is determined before any risk assessment takes place and ... is therefore an integral part of the scientific opinion delivered by the risk evaluators. (CEC, 2000, p 12).

This notion of “prudential approach” is more generically referred to (at least in the U.S.) as part of “science policy” and, in specific, refers to the set of conservative practices that are applied within risk assessments as a matter of established policy. Regardless of the term applied, the core concept is that scientists use predetermined (i.e., established) policy decisions to guide their scientific investigations.² The policy-

2. Perhaps a more accurate statement is that the policy decisions often guide the summarization of the scientific investigations, not necessarily the investigations themselves. For example, the risk assessor usually considers multiple models and their relative merit, but then provides only the high-end predictions from the upper confidence interval of the more conservative model when presenting a summary of the estimated risks to those making the risk management decisions.

influenced science estimates derived from these risk assessments are then reported back to policy-makers, who take the results into account (along with other factors) in determining how to shape policies or establish regulations.

For example, when estimating dose-response functions, estimates of cancer risk posed at high doses often need to be extrapolated to the low doses relevant for regulatory scenarios. As a matter of policy, the U.S. Environmental Protection Agency (EPA) applies a linear dose-response model to make these extrapolations, even though the linear model is not necessarily supported by emerging scientific evidence for many carcinogens and it is likely to overstate risks at low doses. The linear model is — as a matter of policy — EPA’s default assumption, and it is used unless there is a considerable body of compelling scientific evidence supporting a more likely model for a given contaminant.

Why is the linear model used as a matter of policy? The linear model generally is not always justified on scientific merit.³ It often is not the most accurate portrayal of the dose-response function; indeed, nonlinear functions are now believed to be more reflective of dose-response relationships for many carcinogens acting by nongenotoxic mechanisms. Rather, the linear model is applied because it is unlikely to underestimate risks at low dose. That is, the presumption of a linear model is a conservative assumption and has been adopted — as a matter of policy — to minimize the possibility that estimated risks will be understated at the dose of concern. This aspect of the “scientific” process of risk assessment is driven by a policy decision — and the policy decision that underlies the “scientific outcome” is that it is important to err on the side of safety when estimating the risk posed by carcinogens at environmentally relevant exposure levels.

Is it appropriate to err on the side of safety when conducting risk assessments? The answer depends on how the risk assessments are to be used. The use of conservative science policy assumptions arose from how risk assessments were initially conceived — as a process to provide estimates of “safe doses” at which there were no anticipated risks to even the most highly exposed and highly sensitive individuals, with an adequate

3. Many in the scientific community may say that the linear model is justified in the case of purely probabilistic events such as DNA damage, and becomes a better approximation as the variability in sensitivity and susceptibility increases. What is clear is that it is not justified to simply state that a dose-response curve should be linear *a priori*.

margin of safety. In other words, the risk assessors' original mission was to develop estimates of exposure levels that were risk free.⁴

In this context, the use of safety factors and conservative assumptions are a logical practice and are consistent with the narrowly defined mission. For example, this is a suitable approach for the intended use of risk assessments in the context of setting an MCLG, which is a “risk free” *goal*. However, this conservative approach is not appropriate in a risk *management* context such as where to set an enforceable MCL (or in estimating the benefits of a potential MCL). Risk assessments, when applied and interpreted within the context of risk management, need to be stripped of precautionary biases.

The Risk Management Context

Risk management refers to taking the risk characterization output from the risk assessment process (as well as many other factors such as economics, social justice), and deciding what actions, if any, are prudent for reducing the risk (e.g., by deciding whether or not — or at what level — to set an MCL). The risk characterization may include an estimate of the risk borne by an exposed individual (e.g., a $1.0 * 10^{-4}$ lifetime risk of developing cancer), and/or an estimate of the number of adverse health effect cases anticipated (e.g., 1.3 excess cancer cases per year nationwide). These outcomes of the risk assessment are policy-influenced scientific estimates (because precautionary assumptions are routinely used to develop them). These policy-influenced estimates are then fed back to policy-makers for their consideration when developing a course of action.

Because regulatory policy decisions are made based in large part on estimates of risks and benefits developed from the risk assessment process, the use of precautionary assumptions may have a large (and nontransparent) impact on risk management

4. Another reason for these assumptions appearing in risk assessments was that the risk mitigation process in the U.S. tended to focus on one chemical and route of exposure at a time. As a result, it did not account for exposure of populations to multiple pollutants. So, the process of considering one chemical at a time tended to underestimate risk. The use of the default assumptions is in part a response to this, with the hope that it would compensate for this error introduced by the focus on a single chemical and route of exposure when comparing against risk goals. Hence, the default assumptions were not always introduced solely to provide a margin of safety, and not solely to err on the side of safety, in the face of uncertainty in risk estimation.

decisions. Accordingly, the need to separate the precautionary principle out of risk assessments when they are applied in a BCA framework recently has gained increased recognition.

For example, the U.S. General Accounting Office (GAO) recently published an excellent report on this topic, *Use of Precautionary Assumptions in Health Risk Assessments and Benefits Estimates* (GAO, 2000). The GAO report was prepared in response to a request from Congress, and addresses Congressional concerns that EPA's use of precautionary assumptions in estimating health risks "could produce overly optimistic estimates of the benefits of regulatory actions" (p. 3).

The heart of the matter is that precautionary assumptions are built into risk assessments and thus become ingrained in the information (such as benefit-cost analyses) that regulatory decision-makers use to make their policy choices. Because these precautionary aspects tend to overstate risks and benefits (sometimes to a considerable degree), regulatory and other policy decisions are not always based on the best (most accurate) science information available (i.e., the most likely or central tendency estimates of risks and benefits). This potential for using skewed risk and benefits estimates in the risk management context is at odds with the principle of using "good science" in policy-making, and it also is contrary to applicable federal guidelines and statutory provisions, as shown below.

Federal Mandates and Policies on Precautionary Approaches for Drinking Water

As noted above, the application of precautionary assumptions to risk assessments can be a legitimate exercise — it all depends on the intended use of the risk assessment. For example, the Safe Drinking Water Act Amendments of 1996 (SDWAA) mandate that an MCLG must be established as a risk free goal. Accordingly, when risk assessments are used in the MCLG-setting process, they should contain suitable precautionary assumptions. For MCLGs, risk assessments are being used to define a “safe” level, with a margin of safety, for the most sensitive and exposed individuals. Yet even in this context, the risk assessment application has ramifications for risk management, because under the SDWAA the enforceable MCLs must be set “as close to the MCLG as feasible” (unless the Administrator determines that the benefits do not justify the costs).

In contrast, the use of precautionary assumptions is not appropriate in the risk management context of setting MCLs. As provided in the SDWAA of 1996, enforceable standards need to reflect a reasonable balancing of benefits and costs, and the risk reduction benefits should be estimated without the (generally) upward biases embodied in the typical precautionary assumptions of risk assessment. For analysts and decision-makers, the challenge becomes one of trying to isolate and remove the precautionary upward biases when using risk assessments in a benefit-cost or other risk management context (or at least to understand the magnitude of the conservatism, e.g., the percentile of the cumulative density function, so they can understand how much additional confidence in protection is being bought for the policy expenditure).

The SDWAA offer the following directions on the use of science in decision-making for drinking water standards [section 1412(b)(3)] (emphasis added):

- ▶ “...use the best available peer reviewed science and supporting studies conducted in accordance with sound and objective scientific practices” [1412(b)(3)(A)].
- ▶ “...specify, to the extent practicable ... (ii) the expected risk or central estimate of risk” ... as well as “(iii) appropriate upper-bound and lower-bound estimates of risk”...and have “(iv) each significant uncertainty identified in the process of the assessment of public health effects...” [1412(b)(3)(B)].

- ▶ consider within the mandated benefit-cost comparison “...health risk reduction benefits for which there is a factual basis ...that such benefits are likely to occur as the result of treatment to comply...”[1412(b)(3)(C)].

These statutory directives clearly indicate that EPA should develop and consider risk and benefit estimates that reflect the *most likely* outcomes from a potential MCL-setting regulation.⁵ The statutory language acknowledges that uncertainties will exist and that upper and lower bounds need to be presented and taken into consideration. However, the statutory language also is explicit that Congress intended EPA to provide estimates of *expected* (central estimate) risks when comparing benefits to costs and making regulatory decisions. This means that risk assessments as traditionally developed need to be re-interpreted to reflect expected risks for a BCA (rather than using, for example, dose level estimates derived to be safe with a margin of error — such that the estimated risks levels are likely to be over-stated).

EPA conveys a similar philosophy in its *Guidelines for Preparing Economic Analyses* (U.S. EPA, 2000a). Economic Analyses (EAs) are developed by EPA for all “significant” rulemakings (not just drinking water), and are submitted for review to the Office of Management and Budget (OMB) in accordance with Executive Order 12866 (Federal Register, October 4, 1993). EAs contain assessments of the benefits and costs of the options under consideration in a given rulemaking. EPA’s *Guidelines* explicitly state that benefit-cost outcomes should be presented “based on expected or most plausible values” and accompanied by sensitivity analyses to reflect the impact of key assumptions and uncertainties embedded in the analysis (p. 27). “...Uncertainties should be explored through the use of expected values supplemented by upper and lower bounds” (p. 176).

5. The language “likely to occur” then raises the probabilistic aspect of the risk estimates, which in turn leaves the Agency open to considering some percentile of the cumulative density function other than expected value, most likely value (mode), etc. Some may argue that the interpretation of this phrase has led to the incorporation of conservatism into estimates of risk, and is central to understanding the rationality of conservatism. Conversely, arguing against conservatism in this context requires development of an alternative, philosophically and legally sound, interpretation. Nonetheless, it is clear that a focus on central estimates — or at a minimum, a clear presentation of the central tendency risks and benefits (along with high end results) — is essential in the risk management context.

OMB has also issued similar directives in its recommended approaches for developing benefit-cost analyses to support regulatory decision-making. The Office's *Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements* (OMB, March 2000) directs federal agencies to "...calculate the benefits (including benefits of risk reductions) that reflect the full probability distribution of potential consequences ...and include upper and lower bound estimates as complements to central tendency ...estimates" (p. 9). The OMB guidelines further state that "some estimate of central tendency — such as the mean or median — should be used" for developing benefit-cost comparisons and decision-making (p. 15).

Therefore, it is clear from the governing federal statute — as well as in the relevant federal agency guidelines — that standard setting and other risk management activities should be based on central, most likely estimates of risks.⁶ Plausible upper and lower bounds of risk also should be used to reflect uncertainties (and, if available, probability distributions are preferred to bounds). However, the application of risk assessments that embody the typical array of precautionary assumptions will not furnish the necessary "most likely" estimates of risks that are necessary and appropriate for BCA and standard setting

Where and How Precautionary Assumptions Affect BCAs for MCLs

Precautionary assumptions can enter into each component of a risk reduction benefits assessment, and then become compounded when the components are linked together. In this section, we describe each component of a typical analysis, starting with exposure assessment and proceeding to dose-response estimates and valuation. For each component, we outline major uncertainties and variabilities and whether and how they are addressed using standard precautionary assumption practices. Where we can provide empirical evidence, we also show the degree to which the use of the assumptions or uncertainty factors might overstate the estimates of exposure, risk, or value.

Readers should take note that the empirical illustrations of the impact of precautionary assumptions reveal quantitative effects that are case-specific. The results

6. Court rulings can also affect how this problem is approached. Benzene and vinyl chloride-related decisions by courts in the early 1980s apparently have caused EPA to examine its risk management policies, and these court rulings do not necessarily support the idea that risk management activities should be based on central tendency or most likely estimates.

reveal the type and potential magnitude of the impacts of precautionary assumptions, but the results cannot typically be generalized as “assumption X always has a quantitative impact of Y% on the benefit or risk estimate.” The numeric examples provide a sense of how much impact these assumptions have in the specific circumstances applied here, but the magnitude of the impact could be much different in other applications (e.g., when the same assumption is applied to other contaminants, or applied to other sets of circumstances that entail different combinations of assumptions and protocols).

Exposure Assessment

Most drinking water-related risk assessments rely on a standard set of exposure assumptions. These include the assumption that a person consumes 2 liters of contaminant-impacted tap water each day over a 70 year lifetime. These assumptions are used to develop “safe” or “risk free” concentrations. For example, for compounds that pose systemic (noncancer) risks from chronic exposure, EPA uses a zero risk “oral reference dose” (the dose at which no risks are anticipated in humans, including an ample safety margin) and converts it to a Drinking Water Equivalent Level (DWEL) based on these two exposure assumptions. The DWEL is then used to develop the MCLG (typically, the MCLG is set equal to the DWEL, apart from rounding off the values).

In reality, most people consume considerably less than 2 L/day of tap water. The mean daily tap water consumption is slightly greater than 1 L/day (the mean is approximately 1.1 L/day, and 2 L/day is closer to the 90th percentile). In addition, people typically have activity patterns that take them out of the home (e.g., to schools or places of business) where they spend a significant portion of the waking hours and consume a significant portion of their daily water (often from a different water system than the one that serves their residence). People also undertake exposure averting behaviors, such as using bottled water or home treatment devices. Therefore, a typical or expected in-home tap water consumption level is probably well under 1 L/day. If the 2 L/day ingestion rate is applied in a BCA, exposure reductions (and hence risk reduction benefits) would in most cases be more than double the expected real outcome. Fortunately, in recent rulemakings EPA has applied an estimated distribution of daily water consumption in its benefits assessments, so that this potential bias is reduced in recent BCAs.

Duration of exposure is another key variable (especially for contaminants posing chronic rather than acute risks), and 70+ years is the standard assumption applied in risk assessments (73 years was used in the recent National Science Academy evaluation of arsenic risks [NRC, 2001]). However, in reality few people remain in the same community and receive exposures for a duration that is near that long. Median residential duration is 5.2 years in the U.S., meaning that members of half the U.S. households will occupy 14 or more different homes in a typical lifetime.

If a contaminant is present in only 5% of U.S. systems, then the expected additional exposure after a move is 3.4 years or less (.05 probability times 13 or fewer remaining moves, times 5.2 years at each location). Thus, even if a typical person is born in a water system where a contaminant is present at levels of concern, more often than not their total lifetime exposure duration is expected to be 8.4 years or less (5.2 years at the outset, plus an expected 3.4 years (or less) from water served to their future home sites). In this example (in which we are assuming a 5% occurrence of the contaminant in water systems), the use of a lifetime duration of exposure would overstate the more typical or central tendency estimate by a factor of over 8 to 1 (73 years divided by 8.4 years = 8.7). EPA continues to estimate benefits based on lifetime exposure durations rather than more realistic scenarios.

How much might exposure assumptions alter a BCA? If a linear no-threshold dose-response function is applicable, the estimated lifetime cancer risk levels derived from the standard risk assessment (i.e., embodying exposure — related precautionary assumptions of 2L/day over 73 years) would yield a lifetime cancer risk estimate that is nearly 16 times greater than the expected (typical) risk reduction (2 L/day over 73 years implies a lifetime exposure that is 15.8 times larger than a more central estimate of 1.1 L/day over 8.4 years). If the contaminant occurred at elevated levels in 10% of the nation's community water systems (CWS) — rather than 5% as assumed above — then the precautionary assumptions overstate central tendency lifetime exposures by a factor of over 11 to 1 (but if occurrence was 1%, then the expected lifetime exposure is

overstated by a factor of 22.6 when using the standard assumptions).⁷ Table 1 summarizes this information.

In a nonlinear dose-response context, the impact of the assumptions can be greater or less than described above, depending on how anticipated exposures compare to the threshold dose (or, compared to the localized slope for nonlinear models that do not have thresholds). For example, the no-risk MCLG for uranium was recently set at 20 µg/L, using the usual precautionary assumptions of 2 L/day for 70 years (an uncertainty factor of 100 was also applied, as part of the dose-response interpretation, as discussed below). EPA's occurrence estimates indicated 550,000 people were served by systems with waters at a uranium concentration between 20 µg/L and 30 µg/L.

Under the standard precautionary assumptions, all of these 550,000 people would be identified as being exposed to uranium at levels that posed a nonzero risk (i.e., lifetime exposures of up to 150% of the no-risk level). However, given more realistic exposure variable distributions, only 1,300 people out of the 550,000 people in these systems with uranium concentrations over the MCLG were actually expected to have lifetime exposures above "zero risk" level (Raucher et al., 2001). Thus, the benefit of bringing these water systems down to 20 µg/L would be overstated by a factor of more than 415 (i.e., 550,000 people served divided by the 1,300 people who actually would be above the "no-risk" lifetime exposure level at 30 µg/L, but below it at 20 µg/L).

Dose-Response Assessment

Precautionary assumptions are generally most pervasive in the dose-response portion of the risk assessment. The many unknowns involved with dose-response components of human health risk assessments are systematically addressed through the use of uncertainty factors (and other assumptions) that can lead to expressions of risk that may be 100, 1000, or many more times greater than what might be called a "best" or "central estimate." The use of such uncertainty factors and other conservative assumptions (or default values) in risk assessments includes factors for extrapolations

7. Note that with a linear no-threshold dose-response model, the exposure scenarios described here affect the typical (e.g., median) lifetime individual risk level but may not affect the national risk reduction estimates (e.g., number of cases avoided). With a nonlinear model, however, individual risk levels and national estimates of cases avoided will both be impacted by using empirically based exposure distributions rather than precautionary exposure assumptions.

from high doses to low doses, across species (e.g., laboratory rodents versus humans), and other elements.

The type of precautionary assumptions applied and their impact on risk estimates depends on what type of risk the contaminant is expected to pose (i.e., the adverse health effect endpoint) and the type of data available. Consider, for example, *noncancer risks* posed by low-level chronic exposures, such as renal toxicity due to uranium exposure in drinking water (a systemic or noncarcinogenic risk associated with long-term exposure). For uranium, the EPA risk assessment relied on data derived from laboratory animal experiments. A “no effects level” was observed in the laboratory studies of 60 µg/kg/day. To translate this rodent-based finding to humans, Agency risk assessors applied an uncertainty factor of 100 when converting the rodent results into the human-oriented safe dose (the “oral reference dose”) of 0.6 µg/kg/day (i.e., 60 divided by the uncertainty factor of 100). This is how uncertainty is typically addressed for noncarcinogens posing risks from chronic exposure.

There are several similar, pre-established uncertainty factors that are routinely applied to risk assessments for systemics. These often are applied in compound manner, depending on the type and quality of the toxicological studies available and the data they generate. For example, an uncertainty factor of 10 may be applied for one reason (e.g., variations in population sensitivities), and other uncertainty factors of 10 each applied for two other causes (e.g., due to cross species extrapolations, the reliance on only short-term exposure studies, or application of a lab outcome using a “low observed adverse effects level” rather than a “no observed adverse effect level”). This would result in a combined uncertainty adjustment of 1,000 (10 times 10 times 10). The National Commission on Risk Assessment and Risk Management found that two or three safety factors are typically used in assessing noncancer risks, such that a 100- or 1000-fold combined impact is common (GAO, 2000).

How much do these uncertainty factors push the resulting risk or benefit estimates from the central, expected values? The uncertainty factors are applied to develop estimates of suspected thresholds, so the magnitude of the uncertainty factors is not necessarily the same as the magnitude of the potential overestimate of effects for exposures above the true threshold. Still, the impact can be sizable. Research suggests

that a single 10-fold uncertainty factor typically is protective at the 95th percentile, whereas a single uncertainty factor of 3.2 is likely to generate an outcome protective of the median (50th percentile) and beyond (Swartout et al., 1998). The amount of protection depends on whether the factor is applied for inter-subject variability or for one of the causes of uncertainty (interspecies extrapolation, weak data base, etc.). In general, though, the use of an uncertainty factor of 3.2 ensures protection of at least 68% of the population if only inter-subject variability is considered (the percentage protected is higher if the original human data were obtained on sensitive and/or susceptible individuals).

Typically, uncertainty factors are applied that are greater than 3.2 (as noted above, values of 100 or 1000 are common). If there are two uncertainty factors with a combined product of 50, this would yield a 95th percentile result, and if two uncertainty factors had a product of 100 (e.g., where both factors equal 10), the result is protective at the 99th percentile (Swartout et al., 1998, as discussed in the Awwa Research Foundation report by Raucher et al., 2001).

How much might these uncertainty factors impact an oral reference dose or DWEL for a noncarcinogen? An illustration developed in conjunction with an Awwa Research Foundation report suggests that for MTBE, standard EPA procedures would indicate a DWEL in the range of 8.8 mg/L, whereas an alternative approach using distributional data would suggest a standard 26 times higher (or more) (Crawford-Brown, 2000). This difference is based solely on the dose-response components (and does not account for possible changes to reflect central tendency exposure patterns). Although this illustration is MTBE-specific, the results probably are not atypical. Table 2 offers a generic illustration.

For *carcinogens*, there are several precautionary assumptions that typically are applied in a compound manner, making it difficult to differentiate what the “best estimate” might look like given the multiple types of safety margins that enter the analysis. For example, the linear no-threshold model is used to extrapolate observations at high doses to the low doses relevant to most environmental exposures. In conjunction with this, a 95% upper confidence limit often is used to interpret this extrapolation (although some EPA decisions are now based on the maximum likelihood estimate).

Cross-species extrapolation procedures may add additional safety margins. Numerous other factors and assumptions enter the analysis as well (e.g., the sensitivity of the lab species tested, accounting for different types of tumors or tumor sites, adjusting for early mortality).

Some empirical estimates have been made to reveal the degree to which some factors or precautionary assumptions affect risk estimates in the dose-response estimation stage for carcinogens. For example, if the dose-response function for a carcinogen is truly linear, then the use of the 95th upper confidence limit in making the extrapolation from high to low dose leads to an estimated risk at low dose that generally is 2 to 3 times greater than the central or best estimate (D. Crawford-Brown, University of North Carolina, personal communication). If the dose-response relationship is nonlinear, the extent of risk exaggeration created by using the upper confidence limit is likely to be much greater.

There also is empirical evidence available on how the model selected to extrapolate from observed effects at high doses to environmentally relevant low doses can affect the results to a considerable degree. In one illustration, when a linear multi-stage model was applied to benzene data to extrapolate from a 10 ppm dose to a 0.1 ppm dose, the estimated risk at the lower dose level was 4×10^8 times greater than that derived using a log-normal extrapolation model, even though both models yielded similar results at the higher dose range (Reichard et al., 1990). In other words, the choice of the extrapolation model led to a difference in the estimated risk that was 400 million times greater for the linear model than for an alternative dose-response function, when fitted to the same lab data.

The choice of extrapolation model may not always have such an exaggerated impact as shown above for the benzene example, but the model choice can have a significant impact on the estimated risk outcome in many cases. The degree to which the use of a linear model by default might mis-state the risk estimate compared to a nonlinear function (where the latter is more likely) will depend on several important factors. The factors include the degree of nonlinearity in the function (nonlinear functions can be nearly linear, especially over limited exposure or dose ranges). Also, the greater the degree of extrapolation required from the high dose data observations to the low doses of

regulatory relevance, the greater the potential for nonlinearity to make a notable difference in the low dose risk estimate (all else constant).

A recent illustration using MTBE found that the use of a linear model led to estimated results at the mean that were 13 times greater than when a more suitable, nonlinear model was applied (371 cases versus 29 cases) (Raucher et al., 2001).⁸ Because the mean (average) results were influenced by outcomes at the extreme upper tail of the distribution, the results are even more striking when comparisons are made at other points from the distribution. For example, at the 50th and 95th percentile, the nonlinear model predicted 0 and 177 lifetime cancer cases in the modeled population, respectively. In contrast, the linear model predicted median and 95th percentile outcomes of 275 and 967 cases, respectively (Raucher et al., 2001). Thus, the absolute difference in the projected outcomes increases at the upper percentiles, but the percentage difference between the models' outcomes is higher as one compares results at lower percentiles of the distributions.

The recent inquiries over the risk posed by arsenic in drinking water provide some additional useful illustrations. The risk estimates are derived from epidemiological interpretations of data drawn principally from people exposed to relatively high levels of water-borne arsenic in a rural region of Taiwan. There are complex scientific debates over how these Taiwanese data should be interpreted, which in turn have significant implications for what risk levels are implied for U.S. populations at the lower concentrations relevant to the American regulatory alternatives. Taiwanese exposures in the data tend to range in the 100s of $\mu\text{g/L}$, and the relevant U.S. regulatory options are in the 3 $\mu\text{g/L}$ to 20 $\mu\text{g/L}$ range.

In the newly issued report by the National Research Council (NRC) panel assembled to review the evidence on arsenic risks, a linear model was used to interpret the epidemiological data, because this is the default precautionary assumption applied

8. The extent to which the nonlinear model differs in outcome from the linear model depends on the form of nonlinear model selected. In comparing the drinking water concentration of MTBE associated with a lifetime cancer risk of 10^{-4} , the non-threshold nonlinear model yields a concentration 4.2 times greater than the linear model, whereas the nonlinear model with a threshold yielded an estimated 10^{-4} risk concentration 282 times greater than the linear model (Crawford-Brown, 2000).

unless there is “definitive” scientific evidence to indicate an alternative model is proper (NRC, 2001). For arsenic, the scientific opinion is that arsenic’s mode of action for cancer development points toward a sublinear dose-response relationship (but the scientific opinion also is that the dose-response data do not show a strong nonlinearity). For example, the NRC panel initially assembled to review the arsenic risk evidence in 1999 noted that the most plausible scientific evidence supports a sublinear dose-response relationship (NRC, 1999). However, because the available evidence was not sufficiently conclusive, it did not meet EPA’s criteria (as stated in the Agency’s 1996 proposed cancer risk assessment guidelines) for departure from the default assumption of linearity (NRC, 1999; GAO, 2000).

The NRC panel convened in 2001 to review the arsenic data also found that there was an “absence of definitive mode-of-action data” and that the existing “data on arsenic do not provide a biological basis for using either a linear or nonlinear extrapolation” (NRC, 2001, pp. 5 and 6). Absent “definitive” data, the risk assessment process reverted back to the conservative linear model, even though it probably is not the “most likely” model for this substance based on the scientific (albeit nondefinitive) understanding of arsenic’s mode of action.

In comparing estimated risks posed by arsenic at MCL-relevant levels in the U.S., the model choice can make an appreciable difference. For example, at 5 $\mu\text{g/L}$, the lifetime risk estimate using a nonlinear repair-based model leads to a much lower risk estimate than that obtained from the recent NRC panel’s application of the linear default (the repair model is perhaps a most scientifically plausible model for arsenic, reflecting evidence suggesting that arsenic’s likely role in cancer development is through interfering with the repair of DNA damage caused by other agents rather than through direct damage to DNA itself). Using the linear model yields estimates that imply a risk 3 to 5 times greater than that obtained from the data using the repair model, all else equal (Crawford-Brown, 2001).

Another issue in the arsenic risk assessment is whether the estimates should be applied to U.S. or Taiwanese background cancer rates in order to infer the risks posed in the U.S. The NRC panel held divided views on this point, and ended up publishing both results (NRC, 2001). The net result is that the implied risks in the U.S. are 2.5 times

greater when the U.S. baseline is applied (it is these higher results that are shown in the summary tables of NRC, 2001).⁹

If one combines the two elements of arsenic risk assessment, NRC obtains lifetime cancer risk estimates — using the combined assumptions of linearity with U.S. baseline cases — that are 7.5 to 12.5 times greater than are obtained if a (perhaps more) plausible nonlinear repair model is used along with Taiwanese baseline cases (7.5 = 3 times 2.5, and 12.5 = 5 times 2.5). This is not to imply that the NRC's published estimates are necessarily overstated by this amount, but the discussion here does illustrate the degree to which risk results can shift with two scientifically plausible modifications, even for a contaminant such as arsenic that is relatively well understood and for which there is a considerable body of data from human exposures. Table 3 provides a more generic illustration.

Valuation

The assignment of monetary values to reductions in health risks is a controversial issue for many people, because it may appear as if analysts are placing a dollar value on an individual's life. Instead, the analyst is simply using observed data to infer how people value changes in low level risks spread over a large population. There is an extensive empirically based literature available for this purpose (see NRWA White Paper, Raucher, 2001, for a more extensive discussion).

There has been some debate about how to interpret the body of literature for valuing reduced risks of premature fatalities or avoided illnesses. For example, if \$6.1 million (1999 dollars) is viewed as a central estimate for the value of a risk reduction that statistically implies one fewer premature fatality (known as the value of a statistical life, VSL), the issue that arises is how to account for the delayed timing of the risk reduction (e.g., due to latencies and cessation lags in cancer risks). The net impact on the final benefit results typically is not very great (as compared to the exposure and dose-response factors). If no latency is applied, the VSL is \$6.1 million, and if a 20 year latency is used and a 5% discount rate is applied, the adjusted VSL is \$2.3 million. This implies a factor of 2.7 in terms of the difference in values (\$6.1 divided by \$2.3).

9. While there was some disagreement about the use of Taiwan or U.S. background, the members of the panel with the most epidemiological experience elected the use of U.S. numbers.

In reality, the difference factor is likely to be much smaller in the future, since past debates over whether (and how) latency and discounting should be applied seem to have been resolved by the EPA Science Advisory Board (SAB). SAB has consistently advocated the use of discounting and latencies (SAB, 2000; SAB, 2001). Therefore, the possible differences may dwell on the length and trend of cessation lags and the discount rate to apply, which might impact valuation outcomes by a factor of 2 (or less).

Interactions, Compounded Impacts, and Benefit-Cost Comparisons

As shown above, several stages in the risk assessment and valuation steps can lead to a large divergence in risk or benefit estimates when precautionary assumptions are applied. The degree to which a single precautionary factor can alter an outcome (relative to a more central or plausible estimate) can be relatively modest (e.g., a factor of 2 or less) or quite large (e.g., a factor of 10 or even several orders of magnitude greater). However, the most significant implications are revealed when one examines how the outcomes become compounded when the series of precautionary assumptions are linked together in a specific benefit-cost analysis.

How much impact do the typical precautionary assumptions have on an estimated risk level posed by a contaminant at drinking water-relevant concentration levels? There is no single, clear-cut answer, since the degree of cumulative risk or benefit exaggeration depends on many factors. However, the potential magnification of the risk above “expected” levels can be staggering.

For example, if there are 10 sources of uncertainty in risk assessment calculation, and in each case the precautionary assumption introduces only a 2-fold factor of risk (i.e., each assumption alone simply leads to an estimated risk that is twice the expected value), then the cumulative impact would be an estimate more than 1000 times greater than the expected risk (2 raised to the 10th power equals 1,024). Because the individual factors are often greater than 2, the impacts may often be much greater — for example, if there are 10 sources of uncertainty that are addressed using default assumptions that each contribute a 3-fold factor of risk overstatement, then the overall outcome is nearly 60,000 times greater than expected risk (3 raised to the 10th power equals 59,049). If there are only 5 sources of uncertainty that each have a 3-fold impact in terms of overstating risk

reduction benefits, then the cumulative effect would be 243 times greater than a central tendency outcome (3 raised to the 5th power). Table 4 provides a summary illustration.

An Illustration of Compounded Precautionary Impacts: Arsenic Risks

A relevant illustration can be developed using the arsenic risk issues. What is the risk reduction anticipated in a water system of 350 people served and a current arsenic concentration of 11 µg/L if the MCL is set at 10 µg/L? If one estimates these benefits using several of the standard precautionary assumptions such as embodied in NRC (2001), one would calculate risk reductions as follows:

- ▶ Exposures based on 73 years of exposure (NRC also assumed, plausibly, 1 L per day of ingestion). Each person would thus face a lifetime exposure of 293,095 µg of arsenic (73 years * 365 days per year * 1 L/day * 11 µg/L).
- ▶ Assuming post-compliance arsenic is at 80% of the MCL, the lifetime exposure reduction is a 3 µg/L drop in arsenic concentrations (11 minus 8, where 8 = 80% of 10), implying a lifetime exposure reduction due to regulating at 10 µg/L of 79,935 µg.
- ▶ The excess combined bladder and lung risk associated with lifetime exposure is $3.35 * 10^{-4}$ per µg/L, according to NRC's interpretation using the linear model and U.S. baselines cancer rates (NRC, 2001).
- ▶ For each person exposed, the baseline risk is $36.9 * 10^{-4}$, and compliance reduces the risk of cancer by $10.1 * 10^{-4}$ per lifetime. This translates into the equivalent of 0.35 cancer cases avoided over the 350 people over a 73 year time frame (0.00484 cases avoided per year).
- ▶ If annualized compliance costs were \$17,500 per year, the cost per cancer avoided would be about \$3.6 million (\$17,500 divided by 0.00484 cases per year).¹⁰

10. The \$17,500 per year cost estimate is consistent with EPA's estimate, as applied in the EA that accompanied the arsenic rulemaking package of January 2001 (US EPA, 2000b). EPA data suggest an annual cost of \$15,100 per year for a system of 350 people (based on our extrapolating from data for a system with an average population of 230 people). Actual field experience suggests a cost closer to closer to \$19,000 per year (Ramesh Narasimhan, NCS Engineering, personal communication, November 2001). Note too that EPA is revising these cost estimates,

If the same analysis is repeated, but *using central or best estimates of exposures and risks*, then the step-by-step and overall outcomes would be as follows:

- ▶ Exposure estimates are based on a 73 year life span, but also are derived by drawing on (1) a distribution reflecting duration of residence, (2) occurrence-based probabilities of living in an arsenic-impacted water system after any given move, and (3) a distribution of daily water consumption levels (with mean of approximately 1.1 L per day). The “mean” person would thus face a lifetime exposure of 81,875 µg of arsenic (note that this is 27.9% of the 293,095 µg lifetime exposure estimated using the precautionary assumptions above).¹¹
- ▶ Assuming post-compliance arsenic is at 80% of the MCL, the lifetime exposure reduction is a 3 µg/L drop in arsenic concentrations (11 minus 80% of 10), implying a lifetime exposure reduction due to regulating at 10 µg/L of 22,330 µg/lifetime (or 27.3% of the precautionary estimate).
- ▶ The excess combined bladder and lung risk associated with lifetime exposure is $3.35 * 10^{-5}$ per µg/L, based on NRC’s interpretation of the linear model coupled with their application of Taiwanese baseline data (a 2.5-fold decrease, as per NRC, 2001), and combined with a 4-fold reduction if a nonlinear repair-based dose-response function is applied instead of the linear model (based on empirical evidence from Crawford-Brown, 2001). Note that this yields a 10-fold decrease in the unit risk factor relative to the precautionary interpretation above.
- ▶ For the average person exposed, the baseline risk is $1.0 * 10^{-4}$, and compliance reduces the risk of cancer by $2.8 * 10^{-5}$ per lifetime. This yields an expected

and the Agency’s costs for systems of this size are likely to increase. Also, note that a \$17,500 per year systemwide cost implies an average household cost increase on the order of \$150 per year (assuming 3 persons per household, and that households are the entire revenue base for a small system of this size).

11. Note that our simulations show that the mean is well above the median (50th percentile) value for the population. Well over two-thirds (>70%) of the impacted population have exposures below the mean.

reduction in cancer cases equivalent to 0.010 cases over the 350 people served by the system, over a 73 year time frame (0.00013 cases avoided per year).

- ▶ If annualized compliance costs were \$17,500 per year, the cost per cancer avoided would be \$130.4 million (\$17,500 divided by 0.000134 cases per year).

In comparing the outcomes of the two risk assessment scenarios, the combined impact of the two exposure and two dose-response precautionary assumptions is a risk reduction estimate that is over 36 times greater than one might more reasonably expect to be an average or expected outcome (in a cost-effectiveness context, the results suggest the cost per case avoided is 36 times greater). In a risk management context, this significantly alters the manner in which a regulatory decision might be made. Based on the available empirical literature, spending \$3.6 million per cancer avoided may not be an unreasonable investment in public health protection.¹² However, spending over \$130 million per cancer avoided is clearly beyond the realm of a wise investment in public health.

Finally, readers should note that this arsenic illustration (with a 36-fold difference in estimated risk reductions) is atypical in some ways. For example, NRC estimated risk based on “maximum likelihood estimates” rather than the upper confidence limits as is typically done in making high to low dose extrapolations. This avoided one potential source of risk adjustments that might have contributed another factor of 2 to 3 (or more) to the estimated risks. In addition, the reliance on human epidemiological data enabled the risk assessors to avoid cross-species extrapolation issues that typically contribute additional uncertainty factors to the analysis.

12. This may be considered a “reasonable” (if marginal) public health investment to consider because most of these arsenic-related cancers would be fatal, and a central estimate for a 20-year latency-adjusted VSL is \$3.4 million (using a 3% discount rate, for example). Thus, the benefit value of the action would be close to the costs. Other options might have a better payoff, however, and a full incremental analysis of various MCL options, across system size categories, would be much more informative.

Uncertainties and Variabilities have Distinct Implications

To simplify the discussion provided in this paper, the rationale for using precautionary approaches has thus far been conveniently lumped under the rubric of addressing “uncertainty.” In reality, precautionary assumptions are applied because of the presence of two quite distinct concepts — uncertainty and variability. Because important distinctions exist between uncertainty and variability, there are important implications of how uncertainties and variabilities should be addressed as distinct issues when conducting or interpreting risk assessments.

The terms “variability” and “uncertainty” have been broadly used to encompass a multiplicity of concepts, and the precise meaning of these terms varies across disciplines. Risk assessors view variability and uncertainty as very distinct concepts that distinguish between inherent physical (or natural) characteristics on the one hand (i.e., variability) and limitations of knowledge or understanding (as displayed by the risk assessor) on the other (i.e., uncertainty). For example, there is variability in terms of how much of a contaminant a person is exposed to at a given concentration in water — some people ingest more tap water per day than others. There also is variability in body weights, and across human sensitivities to a contaminant. Variabilities are facts of nature and reflect observable differences that exist across people and circumstances. Variabilities are especially prevalent in exposure assessments.

In contrast, uncertainty reflects a lack of understanding about complex phenomena. The dose-response aspect of risk assessment tends to be dominated by uncertainties, including issues such as not knowing the true shape of the dose-response function or how evidence observed in a laboratory species translates into dose-response relationships for humans.

Benefits analyses contain elements of both variability and uncertainty, and the key to developing or interpreting a BCA is to understand how these enter the analysis and influence its outcome. In general, variability cannot be reduced by further research and measurement, but uncertainty can. The distinction between variability and uncertainty can have significant implications for decision-making. Variability is a fact of life, and must simply be recognized in an analysis and risk management context (e.g., some people will be more exposed and/or more sensitive than others). With variability, probability

information can be used to form meaningful averages (expectations) and distributions (e.g., to understand impacts at the 99th percentile) using tools such as Monte Carlo analysis. Uncertainty potentially can be reduced through further scientific research, but in the meantime is best addressed in a BCA through the use of sensitivity analyses (or second order random variables) that reveal the impact of alternative plausible assumptions or models.

With respect to variability, mathematically we know a great deal more about the median or average person and less about people as they move farther from the central portion of the distribution. Uncertainties expand (perhaps without bounds) the further we move away from the median or mean of a variability distribution. In a policy context, this means that as risk managers try to protect more people by moving to higher percentiles of the variability distribution (e.g., a most exposed or most sensitive subpopulation), the uncertainties begin to expand radically (perhaps exponentially). Hence, the results of a risk assessment or BCA will be increasingly distorted as one moves away from the central part of the distribution. This is another reason for trying to ensure that risk managers are presented with (at least) risk and benefit estimates that are drawn from the central portion of the combined risk and benefits distribution.

Irreversibilities

Irreversibility is another important concept to consider in whether and how precautionary approaches are applied. A risk outcome that is likely to be irreversible is one that will have a relatively strong logical and philosophical basis for taking a precautionary approach. For example, species extinction or immediate human mortality are two types of irreversible high-cost outcomes that society will typically wish to avoid (subject to feasibility, cost, and other considerations). In general, the greater the consequences of making a “poor” risk management decision because of uncertainty, the greater the rationale for taking a precautionary tact in managing the risk — and irreversibility is an important element in determining whether a risk is of high consequence.

In drinking water applications, irreversibility arises in the context of whether a given risk arises from acute (as opposed to chronic) exposure. For example, a microbial agent may pose an immediate risk. If a person is exposed to a sufficient number of

pathogens within a short time span, then any associated adverse health effect typically will manifest quickly. Failure to adequately manage the microbial may thus pose an irreversible risk because there is no opportunity to adjust policy or exposure after the fact (the person has been exposed, the risk is thus already borne). If the health endpoint is critical (e.g., potential mortality) and the risk agent is fast acting, and/or not responsive to antibiotics or other medical treatment, then the consequences of exposure are irreversible.

In contrast, risks associated with chronic (long-term, accumulated) exposures are largely reversible. For example, if new evidence emerges about a potential carcinogen that associates a higher risk to drinking water exposures than current data imply, then the risk can still be managed by reducing the level of future exposures. Chronic risks can still be effectively managed except in cases where life-long exposures have already accumulated. Because chronic risks can be managed in this manner, they are “reversible” and current risk management activities should not be overly influenced by precautionary motives.

Conclusions and Recommendations

The blending of science and policy is a necessary byproduct of the facts that (1) uncertainties and variabilities exist in estimating risks and these uncertainties cannot be easily resolved or circumvented, and (2) high-stakes public health policy matters require decision-makers to proceed despite the existence of large and unresolved uncertainties. To address these uncertainties, many policy-based judgments are embedded in how risk assessments are performed. These science policy assumptions tend to be very conservative, based on a precautionary approach that seeks to err on the side of safety when deriving estimates of what dose poses no risks to even the most exposed and sensitive individuals.

In estimating risk levels associated with a concentration of a contaminant in drinking water, the use of precautionary assumptions and adjustment factors is suitable when the calculations are being used strictly in a risk assessment context such as establishing a no risk goal such as an MCLG. However, for BCA and other risk management activities contributing to deliberations on how stringently to set MCLs, it is contrary to good science and statutory directives to carry forward risk estimates that are significantly impacted by myriad precautionary science policy assumptions. The

treatment of these uncertainties tends to inflate the level of risk posed by contaminants, and therefore leads to an overstatement of the benefits of regulations.¹³ The degree to which risk reduction benefits are overstated (if at all) will vary considerably from contaminant to contaminant, depending on many factors. However, the illustrative examples shown above indicate that it is not unreasonable to suspect that benefits derived using precautionary assumptions may be 10, 20, 100, or even many more times higher than one would expect at the mean or median of the benefits distribution.

In view of the potentially significant impact precautionary assumptions can have on estimated risks and associated BCAs, the following recommendations are offered:

1. When EPA develops risk and benefit estimates they should practice full disclosure and provide complete transparency by listing all the precautionary assumptions embedded in a risk reduction benefits assessment.
2. To the extent possible, EPA and other entities should remove precautionary science policy assumptions and provide central tendency estimates for their risk reduction and associated benefits estimates (as well as probability distribution information or, at a minimum, reasonable lower and upper bounds).
3. Comprehensive sensitivity analyses should be applied as an essential tool to help reveal the individual and collective impact of precautionary assumptions on the risk and benefits findings presented to decision-makers, regulatory reviewers, and other stakeholders.

13. It is conceivable that in some cases further research might reveal that a “true” risk level might actually exceed the risk estimated with precautionary assumptions. However, this is very unlikely.

Table 1. Impact of exposure-related assumptions.

Factor	Impact relative to central estimate
(a) Daily tap water consumption (2L/day)	1.8x
(b) Duration of exposure (70+ years)	
— Occurs in 1% of systems	≥ 12.4x
— Occurs in 5% of systems	≥ 8.7x
— Occurs in 10% of systems	≥ 6.1x
(c) Combined impact in lifetime exposure estimate	
— Occurs in 1% of systems	≥ 22.4x
— Occurs in 5% of systems	≥ 15.7x
— Occurs in 10% of systems	≥ 11.0x

Table 2. Impact of illustrative uncertainty factors in reference dose estimates.^a

Issue	Typical factor	Safety margin ^b
(a) Inter-subject variability in sensitivity	10	3.1x
(b) Cross-species extrapolation	10	3.1x
(c) (a) + (b) combined	100	9.8x
(d) Reliance on short-term exposure data	10	3.1x
(e) (a) + (b) + (d) combined	1000	30.5x

a. Dose at which no adverse health effects anticipated, including margin of safety.

b. Relative to 68th percentile, assuming log normal distribution.

Table 3. Impact of cancer risk assessment assumptions.^a

(a) Use of linear dose-response function (relative to suitable nonlinear alternative)	
— MTBE illustration (at mean)	12.8x
— arsenic illustration (repair model)	3x to 5x
(b) Use of 95th upper confidence limit (relative to maximum likelihood)	2x to 3x
(c) Combined illustrative impact (if both (a) and (b) are relevant)	6x to 38.4x
(d) Impact when combined with exposure illustration (Table 1)	66x to 860x

a. Note that results are case-specific, depending (for example) on degree and type of nonlinearity over relevant exposure range, and difference between high dose data points and low doses of regulatory relevance.

Table 4. Compounded impacts.

# of precautionary assumptions	Average impact of each assumption (relative to central estimate)	Cumulative impact (relative to central estimate)
2	7.5x	(7.5 ²) 56x
3	5.0x	(5 ³) 125x
4	4.0x	(4 ⁴) 256x
5	3.2x	(3.2 ⁵) 336x

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